GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2315
ANSWERED ON:29.08.2007
CLINICAL TRIALS FOR DRUGS/SURGICAL PROCEDURES
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has joined WHO's programme of registering clinical trials for transparency and accountability in the process of testing new drugs and surgical procedures on humans;

(b) if so, the details thereof;

(c) whether the Government has to register all clinical trials;

(d) if so, the details thereof;

(e) whether the Indian Council of Medical Research (ICMR) has launched clinical trial registry and decided to allow researchers from neighbouring countries to register their trials with CTRI; and

(f) if so, the details thereof?

Answer

THE MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) to (f) National Institute of Medical Statistics, ICMR in collaboration with WHO and DST, has developed a primary register that includes all the points as required by WHO. It is voluntary and any scientist can register a prospective clinical trial from India and neighbouring countries. However, in order to get registration number, it is mandatory to provide at least 20 point information as required by WHO about the trial. On 20 July 2007, Director General ICMR in the presence of DCGI, WHO Representative and DST Representative and other distinguished scientists and Pharma companies launched Clinical Trial Registry at the National Institute of Medical Statistics, New Delhi.